



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 23, 2013

DELBio Incorporation
C/O Nicky Pan
3F, 6F, No. 252, Shangying Road, Guishan Industrial Zone
Taoyuan County 33341, Taiwan, R.O.C.

Re: K130244

Trade/Device Name: DiaTrue Plus Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, CGA, JJX, JQP
Dated: July 02, 2013
Received: July 5, 2013

Dear Nicky Pan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for

the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.

Director

Division of Chemistry and Toxicology Devices

Office of In Vitro Diagnostics

and Radiological Health

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130244

Device Name: DiaTrue Plus Blood Glucose Monitoring System

Indications for Use:

DiaTrue Plus Blood Glucose Monitoring System is intended for use outside the body (in vitro diagnostic use) at home. It is used for quantitative measurement of glucose level in fresh capillary whole blood sample from the fingertip and the palm. The alternate site testing can be only used during steady-state blood glucose monitoring. The DiaTrue Plus Blood Glucose Monitoring System is intended for use by a single person and should not be shared. In addition, it is intended for use at home as an aid in monitoring the effectiveness of diabetes control program. It should not be used for the diagnosis or screening of diabetes, nor for the testing of neonates.

The DiaTrue Plus Blood Glucose Test Strips are used with the DiaTrue Plus Glucose meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertip and the palm.

The DiaTrue Glucose Control Solutions are for use with the DiaTrue Plus Blood Glucose Test Strips and the DiaTrue Plus Glucose meter as a quality control check that the meter and test strip are working together properly, and that the test is performing correctly.

The DiaLife Mini Blood Glucose Management Software is designed for use in the home with the DiaTrue Plus Blood Glucose Monitoring System to allow users to transmit data from meter to their computer. It is an optional data management software accessory for use with the DiaTrue Plus Blood Glucose Monitoring System.

Prescription Use _____
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use X
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Katherine Serrano -S

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k130244